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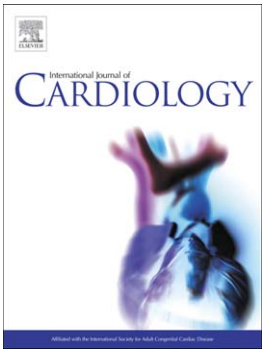

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Title Page

A SYSTEMATIC REVIEW OF TRANSCATHETER AORTIC VALVE IMPLANTATION VIA CAROTID ARTERY ACCESS

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Abstract & Keywords

Background

The carotid artery is a novel access route for transcatheter aortic valve implantation (TAVI). This may represent a viable alternative in patients unsuitable for TAVI via traditional transfemoral access, up to 20%, as well as other access routes such as subclavian, transapical and aortic. This systematic review summarises the current evidence for its safety and feasibility.

Methods

A systematic review was conducted as per the Preferred Reporting Instructions for Systematic Reviews and Meta-analysis (PRISMA) guidelines using five electronic databases.

Results

16 studies were identified, including three prospective cohort studies, one retrospective cohort study, three case series and eight case reports. Data on 74 patients (mean age 76.9 years) was extracted including pre-operative work-up, technical procedure details and outcomes.

This found 1 intraoperative death, 2 further deaths within 30 days, two incidences of transient ischaemic attack, no incidences of stroke, myocardial infarction, carotid

access site complications or infection, 1 patient required new dialysis and 1 patient had an intraoperative dissection which resolved. Follow-up from 30 days to 1 year showed symptomatic improvement and echocardiographic improvement in line with those seen in transfemoral TAVI.

Conclusions

The available data on TAVI via carotid access demonstrate technical feasibility with comparable outcomes to other traditional access routes. A low number of patients, heterogeneous clinical endpoints and relatively short follow-up periods limit formal meta-analysis and firmer conclusions. For patients in which other access routes are impossible, TAVI via carotid access represents a viable and potentially crucial alternative in patients who might otherwise be untreatable.

Keywords: Transcatheter aortic valve, TAVI, carotid

1. Introduction

Patients with severe symptomatic aortic stenosis or regurgitation were classically managed with a valve replacement during open surgery. In the last 15 years, since the first description in 2002 (1), transcatheter aortic valve implantation (TAVI) is a viable alternative for those patients with multiple comorbidities considered at high risk for open surgery (2).

Transfemoral access is the most widely used access route for TAVI, is the least invasive and now also allows for a complete percutaneous procedure (3-5). However, approximately 20% of patients approved for TAVI are not suitable for transfemoral access (6). There are relative and absolute contraindications to the use of this access route such as iliofemoral arteriopathy, tortuosity, severe calcification, abdominal aortic aneurysm or previous vascular surgery. Alternative access routes to the aortic valve include transapical, transaortic and subclavian/axillary access.

The transapical approach is currently the second choice access route in many institutions (7). However, the need for a left anterior minithoracotomy and a left ventricular apical puncture makes this is a far more invasive procedure. This is often still not suitable for patients with some significant comorbidities, which also exclude them from open surgery such as severe respiratory disease or left ventricular dysfunction.

The transaortic approach offers similar drawbacks through the need for a general anaesthetic and an upper ministernotomy (8). It can be challenging from a surgical perspective in patients who have undergone a previous coronary artery bypass graft (CABG) with patent venous grafts. It is likewise unsuitable in patients with severe respiratory disease and those with a 'porcelain aorta'.

Subclavian (or transaxillary) access has been shown to be a safe approach but can also be precluded by previous CABG as with the transaortic approach and also by size of the artery and calcification at the aortic arch (9).

In 2010 Modine and colleagues published the first case report on TAVI via a carotid access route offering a further alternative (10). The purpose of this systematic review is to summarise the current evidence available on TAVI via carotid access and assess its feasibility and safety as an alternative access route.

2. Methods

The review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist for systematic reviews (11).

2.1 Literature Search

Medline (via PubMed), OvidSP, Embase, Google Scholar and Cochrane databases were searched to identify all reports describing TAVI via carotid access. The following 'Medical Subject Headings' (MeSH) search terms were used: "TAVI", "TAVR", "PAVR", "aortic valve replacement", "aortic valve implantation", "aortic valve insertion", "aortic heart valve replacement", "aortic heart valve implantation", "aortic heart valve insertion".

The 'related articles' function was used to broaden the search. Based on the title and abstract, cases were sought in which carotid access was used to perform a TAVI. References of the articles selected were also searched manually. No language restrictions were used. Articles published before 1st January 2002 were excluded as TAVI via any route was not performed before this time. The latest date for this search was 29th March 2016 (the full search strategy can be obtained from TS on request).

2.2 Inclusion Criteria for Review

Any article was included that used either of the common carotid arteries as the primary access vessel for aortic valve replacement.

2.3 Exclusion Criteria for Review

Studies published prior to 2002 were excluded.

2.4 Data Extraction and Validation of Studies

Three reviewers (TS, MH, AC) independently extracted the following data from each study: first author, year of publication, number of patients in study, mean age of patients, sex of patients, co-morbidities, pathology being treated, co-morbidities, contraindications to open surgical repair, contraindications to TAVI via a transfemoral, transapical, transaortic or subclavian approach, approach taken and reason for this, pre-operative work-up, carotid assessment, anaesthetic, equipment used, cerebral monitoring used, qualitative statements on procedure, valve assessment post-procedure, paravalvular regurgitation, mortality, complications, follow-up and outcome at follow-up. Data were also retrieved on the following outcomes of interest: valve assessment post-operatively, paravalvular regurgitation, mortality, neurological complications, vascular access site complications, other complications according to the Valve Academic Research Consortium (VARC-2) criteria (12), follow-up and outcome at follow-up.

2.5 Data Analysis

The outcome measures were mortality, immediate complications, valve function and follow-up of patients. Data regarding valve function were sometimes unavailable whilst those involving follow-up involved dissimilar time spans between reports and was also sometimes unavailable. Overall the data were heterogeneous and formal meta-analysis could not be performed on any extracted data.

3. Results

3.1 Systematic Search Strategy

The systematic search of the databases revealed 712 publications for possible inclusion. Following the removal of duplicates and publications from before 2002, the remaining titles and abstracts were reviewed and irrelevant publications were excluded. This left 36 publications, which were reviewed in their entirety. Of these, 21 were excluded on more detailed inspection of the full text. No additional articles were added from manual review of the references. A total of 16 papers or abstracts were scrutinised and data extracted. The 16 reports comprised three prospective cohort studies, one retrospective cohort study, four case series and eight case reports. Three of the case series had sufficient detail for the data to be extracted as individual cases (6, 13, 14). One group, Azmoun *et al.*, presented or published the same content with increasing patients in their series (15). We selected the published article for data extraction as it provided the most detail on patient characteristics and outcomes. One case series was presented as an oral presentation (16). The search strategy is shown in **Figure 1** and is based upon the PRISMA flow diagram for systematic review (11)

3.2 Patient Demographics, Comorbidities and Contraindications to Open or Other TAVI Access options

In the 16 reports, 74 patients underwent TAVI via carotid access. The mean patient age was 76.9 years (range 27-91 years), with 59.5% of patients being male (ratio M

44:30 F). 69 procedures were performed for severe aortic stenosis, whilst five were performed for aortic regurgitation. One report was in a failed aortic bioprosthesis (17).

All patients were considered unfit for an open procedure. Transfemoral access was contraindicated due to vessel disease, calcification, tortuosity, significant risk of rupture and risk of distal emboli. The transapical approach was contraindicated chiefly due to severe pulmonary disease or previous coronary artery bypass graft (CABG). Finally the subclavian route was mostly precluded due to difficult anatomy such as angulation, stenosis and calcification; or again from previous CABG.

A summary of baseline patient characteristics, comorbidities, risk stratification scores and reasons for avoidance of other traditional endovascular techniques is presented in **Table 1** and **Table 2**.

Figure 1. PRISMA Flowchart

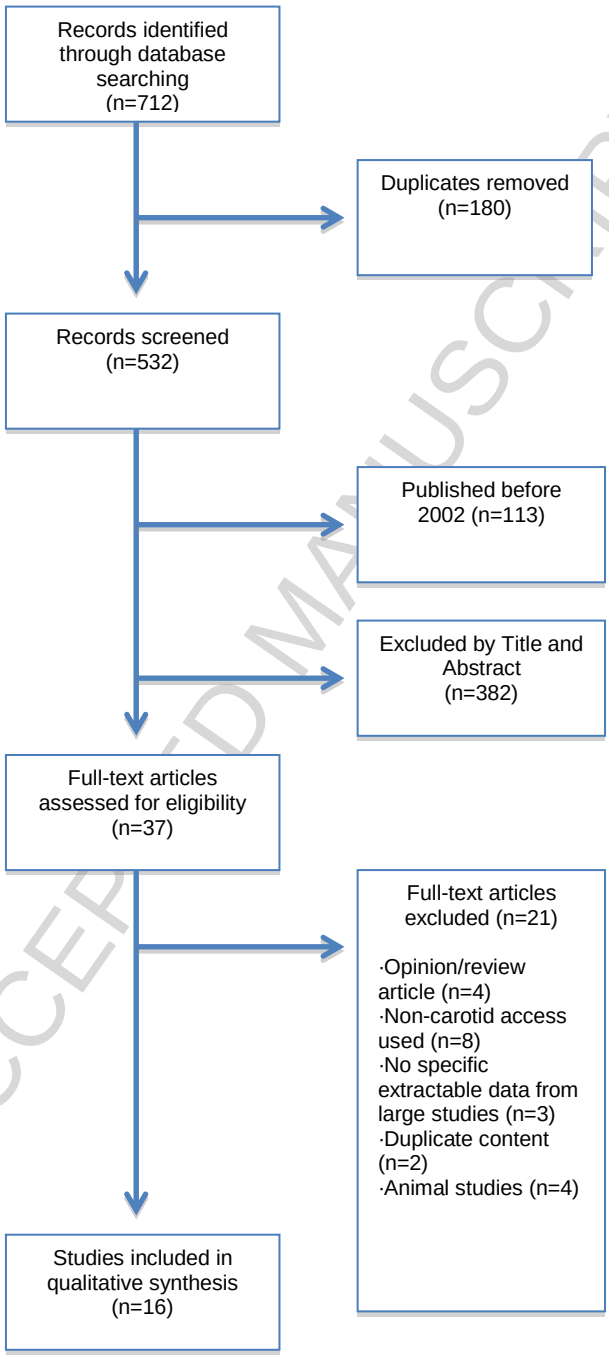

Table 1. Baseline Characteristics

First author; Year	Design	Specific study interest	Exclusion Criteria	No. patients	Age (years)	M:F	Pathology	Co-morbidities	Euroscore / STS
Huczek 2015	Case series (Case 1)	-	-	1	74	F	AS. Mean gradient 37 mmHg, valve area 0.45cm^2, LV EF 60%.	CABG, ascending aortoplasty, previous AVR with bioprosthesis, NYHA Class III, AAA, thoracic aortic aneurysm, HTN, CKD, hypothyroidism, right masterctomy, GI bleed, early stage colorectal CA	STS 4.3%
Huczek 2015	Case series (Case 2)	-	-	1	84	M	AS. Mean gradient 47mmHg, peak gradient 86mmHg, jet velocity 4.5m/s, valve area 0. 8cm^2,	CABG (LIMA to LAD), porcelain aorta, HF NYHA Class III	STS 8.8%
Daly 2015	CR	Previous mitral valve replacement	-	1	80	F	AS.	Rheumatic heart disease, MVR, AF, CKD (eGFR 49mL/min), severe COPD (FEV1 46% predicted).	Logistic Euroscore 42.6%, STS 17.6%
Huber 2015	Case series (Case 1)	AR due to degenerated stentless Shelhigh conduits (Aortic root replacement)	-	1	84	M	AR. LV dilatation (55mm). Severely reduced LV EF.	Previous ascending aortic aneurysm (52mm) managed with elective composite valve-graft conduit replacement of the aortic root, replantation composite valve-graft conduit replacement of the aortic root, replantation of the coronary arteries and bypass of the right coronary artery. CKD on haemodialysis. HF NYHA III.	Euroscore II 14%, STS 8.5%
Huber 2015	Case series (Case 2)	AR due to degenerated stentless Shelhigh conduits (Aortic root replacement)	-	1	74	M	AR. Aneurysm of 54mm at distal anastomosis of composite-graft and native aorta.	Previous acute type aortic dissection. Replacement of aortic valve and ascending aorta with stentless Shelhigh valved conduit. Multiple ischaemic strokes due to transient cerebral hypo-perfusion following this. Frailty (BMI 19.6 kg/m^2). HF NYHA IV.	Euroscore II 3.6%, STS 3.9%
Huber 2015	Case series (Case 3)	AR due to degenerated stentless Shelhigh conduits (Aortic root replacement)	-	1	56	M	AR. LV EF 30%.	ADPKD, unilateral left renal agenesis. Previous Type A aortic dissection managed with emergency aortic valve replacement with graft conduit. Subacute infective endocarditis with Strep. bovis 3 years later, followed by abscess formation around the mechanical valve requiring replacement of aortic valve and ascending aorta with stentless Shelhigh valved conduit. Chronic renal failure requiring haemodialysis via fistula. Pacemaker for LV EF 30% with LBBB. HF NYHA Class IV.	Euroscore II 16%, STS 9.4%
Pozzi 2015	Prospective cohort study	Previous ipsilateral carotid endarterectomy	Carotid diameter < 6.5mm	9	84.6 +/- 3.6 (range 79-91)	4 M:F 5	AS. Mean gradient 51.5 ± 11.5 mmHg, valve area 0.40 ± 0.09cm^2, , mean jet velocity 4.7 ± 1.1 m/s.	HTN 9 (100%), DM 1 (11.1%), hypercholesterolemia 6 (66.5%), COPD 1 (11.1%), frailty 2 (22.2%), previous CABG 2 (22.2%), CKD 5 (55.5%), previous CVA/TIA 4 (44.5%), AF 4 (44.5).	Euroscore II 7.96 ± 6.51%, STS 7.01 ± 9.62 %
Thourani 2015	Retrospective cohort study	Retrospective cohort of 469 patients who underwent TAVI via alternative access routes	Carotid diameter <8mm or evidence of stenosis	11	68.9 +/- 23.6	5 M:F 6	AS. Mean gradient 42.0 ± 18.1 mmHg, valve area 0.62cm^2 ± 0.17, jet velocity 4.3 ± 0.6m/s, LV EF 45.5 ± 17.4%	Cerebrovascular disease 3 (27.3%), DM 4 (36.4%), mod-severe COPD 6 (54.6%), dyslipidaemia 9 (81.8%), HTN 9 (81.8%), history of infective endocarditis 1 (9.1%), immunosuppression 1 (9.1%), CKD 5 (45.5%) (none on dialysis), peripheral vascular disease 8 (72.7%), previous CVA 1 (9.1%), previous CABG 6 (54.6%), previous valve procedure 9 (81.8%), Heart failure NYHA 3 or 4 in 10 (90.9%), previous MI 2 (18.2%). THESE ARE THE SAME CONFIRM.	STS 17.1% ± 8.8%
Benhalla 2015	CR	Via prosthesis carotid artery	-	1	83	M	AS. Severely calcified aortic bioprosthesis. Mean gradient 53mmHg, valve area 0.8cm^2, LV EF 40%.	HF (due to severe degenerative aortic bioprosthesis), DM, HTN, COPD, peripheral artery disease, coronary artery disease.	Euroscore II 36%
Azmoun 2014	Prospective cohort study	-	Carotid diameter <6mm or stenosis, calcification or major tortuosity	19	82.2 +/- 5.9	14 M:F 5	AS. Mean gradient 42.3 ± 15.9 mmHg, LV EF 49 ± 16%	Severe peripheral vascular disease. Occlusion or severe stenosis in iliofemoral arteries in all patients. Large AAA (>50mm) in 1 patient (5.3%), previous abdominal aortic endoprosthesis in 2 patients (10.5%), previous aortobifemoral bypass in 3 (15.8%), previous axillo-bifemoral bypass in 1 (5.3%).	Logistic EuroScore 25.2 ± 15.7%, STS 11.9 ± 5.1%.
Maureira 2014	CR	AR due to degenerate ascending aorta replacement	-	1	68	M	AR. LV dilatation (72mm). LV EF 52%.	HTN, DM II, severe COPD (FEV1 <40%), previous Type A Aortic dissection, replacement of ascending aorta. Stable chronic aortic dissection (aortic arch extending to abdominal aorta just below right renal artery, with no innominate artery involvement). HF NYHA III.	Logistic EuroScore 11.05%, STS 5.43%

Modine 2014	CR	-	-	1	85	M	AS. Valve area 0.53cm^2, mean gradient 41mmHg, max gradient 61mmHg, peak jet velocity 4.2m/sec, preserved LV EF.	Previous stroke, subdural haematoma, bronchiectasis, AF, peripheral artery disease, laryngeal neoplasm, nephrectomy, CKD.	Logistic Euroscore 46.48%, STS 13.4%.
Rajagopal 2014	CR	-	-	1	81	M	AS. Peak gradient 54 mmHg, valve area 0.6cm^2, LV EF 42%.	Previous CABG (LIMA to LAD, 2 vein grafts, shown to be patent). DM II, HTN, Stage 3 CKD, severe asthma.	Euroscore II 26.9%, STS 25.1%
Magalhaes 2013	CR	Combined left carotid endarterectomy, left carotid-subclavian tunnel bypass and transcartoid TAVI	-	1	81	M	AS. Mean gradient 56mmHg, valve area 0.57cm^2, mean gradient 56 mmHg, LV EF 65%	HF NYHA Class III. Episodes of presyncope. DM, HTN, dyslipidaemia, previous aortic bi-iliac and aortic-left renal artery bypass due to Leriche's Syndrome. Previous CABG (bypass grafts shown to be patent). Previous right carotid endarterectomy.	Euroscore II 25.9%
Khan 2013	Case series via oral presentation	-	-	7	82	1 M:F 6	AS. (LV EF <40% in one patient)	Previous CABG 2 patients, previous MI 1 patient, CKD 3 patients.	Logistic EuroScore 12.43 ± 2.87%
Guyton 2013	Case series (case 1)	-	-	1	80	F	AS.	HF NYHA Class IV. Porcelain ascending aorta, calcification of both subclavian arteries, mod-severe pulmonary dysfunction, frail, calcification of costal cartilages and narrow rib spaces.	Not reported
Guyton 2013	Case series (case 2)	-	-	1	27	M	AR.	Shone's complex, congenital AS, coarctation of the aorta, congenital mitral stenosis. 6 previous sternotomies (repair of coarctation of aorta, open mitral valvuloplasty, bileaflet mechanical aortic prostesis, ICD implantation). Ross-Konno procedure and removal of infected aortic prosthesis. Group B streptococcal endocarditis. Further homograft aortic root and pulmonary bioprosthetic valved conduit. HF NYHA Class III.	Not reported
Guyton 2013	Case series (case 3)	-	-	1	78	M	AS. LV EF 25%	3 vessel coronary disease and AS. Porcelain aorta found at sternotomy bypass completed but valve not replaced. (Patent grafts at 1 year). Severe lung disease requiring home oxygen. Severe peripheral vascular disease.	Not reported
Modine 2012	Prospective cohort study	-	Carotid diameter <7.5mm	12	85 (range 72-88)	8 M:F 4	AS. Mean gradient 51 mmHg (range 46-54mmHg), mean LV EF 0.60 (range 0.42-0.72mmHg).	HF NYHA class III/IV (50%), pacemaker (16%), AAA (33%), peripheral vascular disease (91%), CKD (25%). 7 patients left/right internal thoracic artery bypass.	Logistic EuroScore 16 % (range 9-20%), STS 6 +/- 5
Mouillet 2011	CR	-	-	1	90	F	AS. Valve area 0.56cm^2. Mean gradient 82 mmHg. LV EF 55%.	HTN, severe peripheral vascular disease, hypercholesterolaemia, history of pulmonary TB. HF NYHA Class II.	Logistic EuroScore 53.29%
Modine 2010	CR	First case report	-	1	89	M	AS. Peak gradient 75mmHg, valve area 0.8cm^2, LV EF 50%.	Type 1 Aortic arch, pacemaker. HF NYHA III.	Logistic EuroScore 14.6%

Table 1 Abbreviation List

AS	Aortic stenosis
AR	Aortic regurgitation
MVR	Mitral valve replacement
CKD	Chronic kidney disease
HF	Heart failure
NYHA	New York Heart Association
ADPKD	Autsomal dominant polycystic kidney disease
HTN	Hypertension
TIA	Transient ischaemic attack
CVA	Cerebrovascular accident
AAA	Abdominal aortic aneurysm
LV EF	Left ventricle ejection fraction
M	Male
F	Female
CR	Case report
DM	Diabetes mellitus
"-"	Indicates information not reported

Table 1. Shows the baseline characteristics of patients involved in each of the studies. Specifically looking at the pathology leading to the need for intervention, and the co-morbidities of the patient groups of each study.

Table 2. Reason for approach selection

First author; Year	Stated reason open surgery contraindicated	Stated reason Transfemoral TAVI contraindicated	Stated reason Transapical TAVI contraindicated	Stated reason subclavian TAVI contraindicated	Stated reason direct aortic approach contraindicated	Carotid approach used	Reason for carotid side selection
Huczek 2015	High risk	-	Previous CABG with LIMA to LAD, saphenous vein grafts to right coronary and marginal branch.	-	-	L	-
Huczek 2015	High risk	Severe atherosclerosis iliac arteries	Previous CABG with LIMA to LAD	-	-	L	-
Daly 2015	Excessive risk due to frailty and multiple co-morbidities.	Small iliofemoral arteries <6mm	Severely impaired pulmonary function with poor pulmonary reserve, calcification and posterior displacement of the cardiac apex	Small subclavian arteries <6mm	Severely impaired pulmonary function with poor pulmonary reserve, calcification and posterior displacement of the cardiac apex	L	-
Huber 2015	High risk due to CKD and severely reduced LV EF.	High risk of distal embolisation due to bilateral thrombosed iliac aneurysms with decreased lumen diameter.	No data to support use of TA implanted valve in AR.	Unfavourable angulation of left subclavian	-	R	-
Huber 2015	High risk due to prior ischaemic stroke and frailty.	High risk of rupture due to aneurysm of 54mm at distal anastomosis of composite-graft and native aorta.	No data to support use of TA implanted valve in AR.	High risk of rupture due to aneurysm of 54mm at distal anastomosis of composite-graft and native aorta.	-	R	Favourable angulation and minimal atherosclerosis.
Huber 2015	High risk due to advanced age and reduced mobility	Chronic aortic dissection from left subclavian artery to both iliac arteries.	No data to support use of TA implanted valve in AR.	Chronic aortic dissection from left subclavian artery to both iliac arteries. Right subclavian route restricted by presence of pacemaker.	-	L	-
Pozzi 2015	-	-	-	-	-	L	More direct approach in the axis of the aortic valve and so easier introduction and deployment of the prosthetic valve. Reduced distance to aortic annulus and direct trajectory allows exact control of catheters and guide wires.
Thourani 2015	Combined risk of death and irreversible severe morbidity >50%.	Ileofemoral vessel size, tortuosity, calcification.	LV EF <15% or severe COPD with FEV1 <35%	-	Porcelain aorta or previous median sternotomy	R	-
Benhalla 2015	Not fit	Severe peripheral vascular disease – specifically iliofemoral lesions	-	Calcification in innominate artery. Subclavian diameter 5-6mm with calcification	-	L	-
Azmoun 2014	-	Occlusion or severe stenosis in iliofemoral arteries in all patients. AAA (>50mm) in 1 patient, previous abdominal aortic endoprosthesis in 2 patients, previous aortobifemoral bypass in 3, previous axillo-bifemoral bypass in 1.	Previous CABG with patent internal thoracic artery grafts.	-	-	8 R, 11 L	Most suitable chosen based on preoperative contrast enhanced CT
Maureira 2014	High risk pulmonary complications & prolonged ventilation (Severe hypoxaemia at rest and impaired spirometry).	-	Insufficient prosthesis size. Severe pulmonary dysfunction.	Less easy to access and control in event of vascular complication (vs carotid access)	-	R	-

Modine 2014		Iliofemoral arteries unsuitable due to circumferential calcification and tortuosity.	Severe respiratory dysfunction	Narrow calcified left subclavian artery.	Severe respiratory dysfunction	L	
Rajagopal 2014	Unsuitable for GA	Severe calcific/stenotic atheromatous disease in lower abdominal aorta and iliac arteries. Minimum lumen diameter in common iliac arteries 4.6mm right, 5.5mm on left.	Unsuitable for GA	Patent, dependent LIMA graft.		R	Direct coaxial angle of the approach
Magalhaes 2013	High risk candidate.	Calcification and severe stenosis of both iliac and femoral arteries.	Four bypass grafts including LIMA-LAD.	Four bypass grafts including LIMA-LAD. Unfavourable anatomy of innominate artery due to calcified stenosis and steep angulation.	Four bypass grafts including LIMA-LAD.	L	Unfavourable anatomy of innominate artery due to calcified stenosis and steep angulation. Prior right-sided endarterectomy.
Khan 2013	Not suitable or high risk	Extensive iliac and femoral vascular disease	-	Precluded - unspecified reason	Precluded - unspecified reason	R	-
Guyton 2013	High risk candidate	5mm calcified iliac arteries at junction with aorta	Calcification of costal cartilages and narrow rib interspaces	Calcification of both subclavian arteries.	Calcification of costal cartilages and narrow rib interspaces	R	-
Guyton 2013	High risk candidate	Right external iliac occlusion. Small left common femoral artery (5-6mm)		Chronically occluded left subclavian artery, right subclavian artery diameter 6.5mm.	Previous sternotomy	R	RCCA larger diameter
Guyton 2013	Porcelain aorta, previous bypass, severe lung disease, depressed EF.	Severe peripheral artery disease in lower extremity	Porcelain aorta, previous bypass, severe lung disease, depressed EF.	Severe disease in subclavian arteries	Porcelain aorta, previous bypass, severe lung disease, depressed EF.	R	-
Modine 2012	High risk candidate	Extremely tortouse and stenosed.	CT angiography suggest diameter and patency not suitable	Diameter and patency not suitable as suggested by CT angiography.	-	L	More direct approach in axis of aortic valve. Convenient for procedure room.
Mouillet 2011	High risk candidate	Bilateral subocclusive calcifications in iliac arteries.	Aortic annulus greater than 24mm.	Left subclavian narrow (6.2mm) and calcified. Right subclavian not in same access as ascending aorta.	-	L	Straight path from LCCA to aortic annulus allowing easy and quick implantation.
Modine 2010	High risk candidate due to advanced age.	Severe tortuosity of abdominal aorta.	Not stated.	Severe tortuosity of right subclavian. Calcification of left subclavian artery. Pacemaker gives high risk of infective endocarditis.	-	L	Type 1 aortic arch.

Table 2 Abbreviation List	
CKD	Chronic kidney disease
LV EF	Left ventricle ejection fraction
GA	General anaesthetic

Table 2 shows why other approaches were not selected in each study. Furthermore it states which carotid side was used in each study and the reason for this if stated.

3.3 Procedural technique

Three types of TAVI device were used in all studies found; the CoreValve porcine pericardial device (Medtronic, Inc., Minneapolis, Minnesota), the balloon-expandable Edwards SAPIEN bovine pericardial device (Edwards Life Sciences, Irvine, California) and in one case the Evolut R valve (Medtronic, Inc., Minneapolis, Minnesota) . The left common carotid are was used for access in 41 cases, with the right side used in 33. Where reported the procedure was done under local anaesthetic in 22 cases (41.5% of those reported), and general anaesthetic in 31 cases (58.4% of those reported), with no cases requiring conversion from local to general anaesthetic. In one case general anaesthetic was used for placement of the Dacron prosthesis prior to the TAVI procedure performed under local anaesthetic (17). Individual procedure techniques are detailed in **Table 3**.

Table 3. Technical notes

First author; Year	Reported work-up investigations	Carotid assessment	Circle of Willis assessment	GA / LA	In procedure cerebral monitoring	CO results	Valve Make & Size	Sheath size	Technical equipment used	Pre-implant balloon valvuloplasty	Rapid ventricular pacing	Guidance techniques	Surgical adjuncts and technical notes.	Qualitative statements on procedure
Huczek 2015	MSCT, carotid Doppler, vertebral artery Doppler	-	-	GA	CO + TCD	CO – no hypoperfusion. TCD – 160 HITS in 65mins. 14mins of low flow in left MCA.	Evolut R 23mm valve	14Fr 'sheathless delivery system'	-	-	-	TOE	Straight tip guidewire, exchanged to Super Stiff Ampltaz guidewire. Initial 6Fr introducer sheath then 14Fr 'sheathless' delivery system	Straight delivery route from access site to annulus level, excellent control during frame flaring with no need for repositioning
Huczek 2015	Angio CT, carotid Doppler, verterbral artery Doppler	-	-	GA	CO + TCD	CO – no hypoperfusion. TCD – 200 HITS in 72mins. 9mins of low flow in left MCA	29mm Medtronic CoreValve	18Fr	-	-	-	TOE	-	-
Daly 2015	Carotid Doppler study, 3D TTE and MSCT.	Carotid diameter ≥7.5mm. Disease free	Patent	LA	-	-	26mm Medtronic CoreValve	18Fr	-	Y	Y	Fluorscopic & TTE	-	-
Huber 2015	Carotid Doppler, vertebral artery Doppler, TTE, cardiac catheterization, MSCT, cerebral MR angio.	Carotid diameter >7mm.	Patent	GA	-	-	29mm Medtronic CoreValve	18Fr	5Fr sheath used for femoral access and pigtail. Temporary pacemaker catheter in right ventricle.	-	Y	Fluoroscopic & TOE (in 2/3)	-	Short distance from puncture site to valve site gives well-controlled release of prosthesis
Huber 2015	Carotid Doppler, vertebral artery Doppler, TTE, cardiac catheterization, MSCT, cerebral MR angio.	Carotid diameter >7mm.	Patent	GA	-	-	29mm Medtronic CoreValve	18Fr	5Fr sheath used for femoral access and pigtail. Temporary pacemaker catheter in right ventricle.	-	Y	Fluoroscopic & TOE (in 2/3)	-	As above
Huber 2015	Carotid Doppler, vertebral artery Doppler, TTE, cardiac catheterization, MSCT, cerebral MR angio.	Carotid diameter >7mm.	Patent	GA	-	-	29mm Medtronic CoreValve	18Fr	5Fr sheath used for femoral access and pigtail. Temporary pacemaker catheter in right ventricle.	-	Y	Fluoroscopic & TOE (in 2/3)	-	As above
Pozzi 2015	Carotid Doppler, vertebral artery Doppler, TTE, coronary angio, CT scan.	Carotid diameter ≥6.5mm.	-	GA	CO	Not below 55%	Medtronic CoreValve	18Fr	-	-	-	-	-	-
Thourani 2015	Carotid Doppler, TTE.	Carotid diameter >8mm. No stenosis.	-	-	CO		Edwards SAPIEN 23mm (n=7), 26mm (n=4)	-	6Fr sheath in femoral artery and pigtail catheter. Temporary right ventricular pacemaker (via femoral	Y	Y	Fluoroscopic & TTE	Bypass shunt in distal carotid arteriotomy to maintain cerebral perfusion.	-

								vein)						
Benhalla 2015	TTE, TOE	Carotid diameter ≥6.5mm.	-	GA for Dacron prosthesis, then LA	Electroencephalogram (EEG)		Medtronic CoreValve	-	-	-	-	Fluoroscopic	Use of 8mm prosthesis carotid in Dacron to facilitate procedure. (Placed under GA via endarterectomy and connected end to side).	
Azmoun 2014	Coronary angio, TTE, pulmonary function testing, MSCT	Carotid diameter >6mm. No stenosis, calcification or major tortuosity.		LA	Awake tests		Edward SAPIEN 26mm (n=1), 29mm (n=3), Medtronic CoreValve 26mm (n=3), 29mm (n=5), 31mm (n=6)	18Fr or 20Fr	5Fr femoral/radial sheath for angiographic visualisation.	Y	Y	Fluoroscopic	Passive antegrade carotid perfusion through a temporary femoro-carotid shunt. In two patients with loss of consciousness on cross-clamping	More direct route & shorter distance to valve enhanced sheath and catheter stability and improves movement precision. More accurate prosthesis positioning.
Maureira 2014	CT angio, Transcranial Doppler echo	Disease free	Patent	-	-	-	31mm Medtronic CoreValve (oversized 10%)	-	-	-	-	Fluoroscopic	-	Easier to access and control
Modine 2014	Not reported	Carotid diameter >7mm. No stenosis. (10mm between aortic annnulus and ostium of left coronary artery.)	Patent	GA	CO		Edward SAPIEN 26mm	19Fr	-	Y	Y	Fluoroscopic	-	Found positioning and control considerably easier than transfemoral.
Rajagopal 2014	CT angio, Carotid MRI	Carotid diameter ≥8.5mm.. (LCCA 6.5mm with moderate (60%) stenosis).	Patent	LA	CO + awake tests	Minimum 56%	Medtronic CoreValve 26mm	18Fr	Temporary pacing wire via right femoral vein. Invasive arterial BP monitoring via radial artery.	Y (20mm balloon)	Y (180bpm)	Fluorscopic & TTE	-	-
Magalhaes 2013	Coronary angio, CT scan	Carotid diameter ≥8.3mm. High grade stenosis at bifurcation.	Patent	GA			Medtronic CoreValve 26mm	18Fr	-	N	-	-	(Left endarterectomy performed first). Graft tunnel bypass between left subclavian and LCC distal to intended sheath access site ensuring cerebral perfusion throughout procedure.	-
Khan 2013	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Guyton 2013		-		GA	CO		Edward SAPIEN 23mm	22Fr	6Fr sheath in right femoral artery for temporary right ventricular pacemaker and	Y (20mm balloon)	Y	Fluoroscopic	Javid shunt (arterial antegrade carotid perfusion with retrograde placement of delivery sheath and completion of TAVR	-

									pigtail for angiograms.				through this due to CO drop in initial clamping) (passive antegrade carotid perfusion) (all 3 the same)	
Guyton 2013		-		GA	CO	Stable throughout	Edward SAPIEN 26mm	24Fr	6Fr sheath in left femoral. Pigtail catheter for angiography.	N (severe AR)	Y	Fluoroscopic	Javid shunt connected to axillary artery Dacron graft and inserted antegrade into distal carotid artery. [2+ paravalvular regurgitation required a second 26mm valve to be deployed within the first 2mm more aortic in position.]	-
Guyton 2013		Carotid diameter >8mm. Disease free. Moderate stenosis in right internal carotid.		GA	CO	Stable throughout	Edward SAPIEN 26mm	24Fr	Left femoral artery pigtail and right ventricular pacing. Right groin 12Fr sheath for valvuloplasty and angiography.	Y	Y	Fluoroscopic	Javid shunt placed antegrade into common carotid, and 7Fr sheath in retrograde common carotid.	-
Modine 2012	Carotid Doppler, verterbral artery Doppler, TTE, iliofemoral & coronary angio, CT angio of subclavian, carotid & verterbral arteries. Cerebral MRI to access circle of Willis. Transcranial ECHO Doppler in some.	-		GA	CO	-	Medtronic CoreValve 26mm or 29mm	18Fr	6Fr catheter in femoral artery for angiography and pacing wire.	Y	Y (during valvuloplasty only)	Fluoroscopic	-	-
Mouillet 2011	Coronary angio, multidetector CT (MDCT), angio MDCT.	Carotid diameter 6.3mm.	Patent	-	-	-	Medtronic CoreValve 29mm	18Fr	-	Y	-	-	-	-
Modine 2010	Carotid Doppler, vertebral artery Doppler, CT angio.	Carotid diameter 7mm. Disease free.		LA	-	-	Medtronic CoreValve	18Fr	-	Y	-	-	-	Good implantation stability and ease of delivery.

Table 3 shows the details of the operations in each study including the work-up carried out, the anaesthetic used, equipment required to perform the procedure and finally any qualitative reports from the authors.

Table 3 Abbreviation List

GA	General anaesthetic
LA	Local anaesthetic
CO	Cerebral oximetry
TTE	Transthoracic echocardiogram
TOE	Transoesophageal echocardiogram
TCD	Transcranial Doppler monitoring
HITS	High intensity signals
MSCT	Cardiac multi-slice computer tomography (contrast enhanced electrocardiogram gated)

3.4 Assessment of mortality

There was one intraoperative death due to aortic annulus rupture during balloon valvuloplasty (15). There were two further deaths within 30 days, one from multisystem organ failure and one from haemopericardium(15, 16). The overall mortality across the studies was 4.1%.

3.5 Other perioperative outcomes

A number of perioperative outcomes was reported according to the VARC-2 endpoint definitions (12). These were recorded over a range of follow-up periods from 1 month to 1 year. There were no incidences of myocardial infarction. There were no incidences of clinical stroke, however one study reported a new ischaemic lesion on diffusion weighted-MRI (6). Two transient ischaemic attacks were reported (10, 18). 10 patients required a transfusion of at least 2 units of packed red cells (8, 15, 19). One patient required new dialysis for acute kidney injury (19). One patient had a dissection intraoperatively which resolved (10). The most common complication was the need for insertion of a permanent pacemaker, which was required in nine cases (12.2%) (8, 15, 18, 20-22). The reasons for each pacemaker insertion are detailed along with the individual outcome data for each study in **Table 4.**

3.6 Echocardiographic outcomes

All but three studies reported the incidence of postoperative paravalvular regurgitation - equivalent to the leak around the new valve. 16 patients (21.6%

of those reported) were found to have mild paravalvular regurgitation (13, 15, 19, 22, 23), while three patients (4.1% of those reported) were found to have moderate paravalvular regurgitation (8, 15, 24); there was no incidence of severe paravalvular regurgitation.

7 studies reported transvalvular mean pressure gradients at baseline and post-operatively (6, 8, 15, 17-20). These demonstrated an adequate improvement in mean gradient values from a mean of 45.4mmHg to 11.8mmHg, as individually summarised in **Figure 2.**

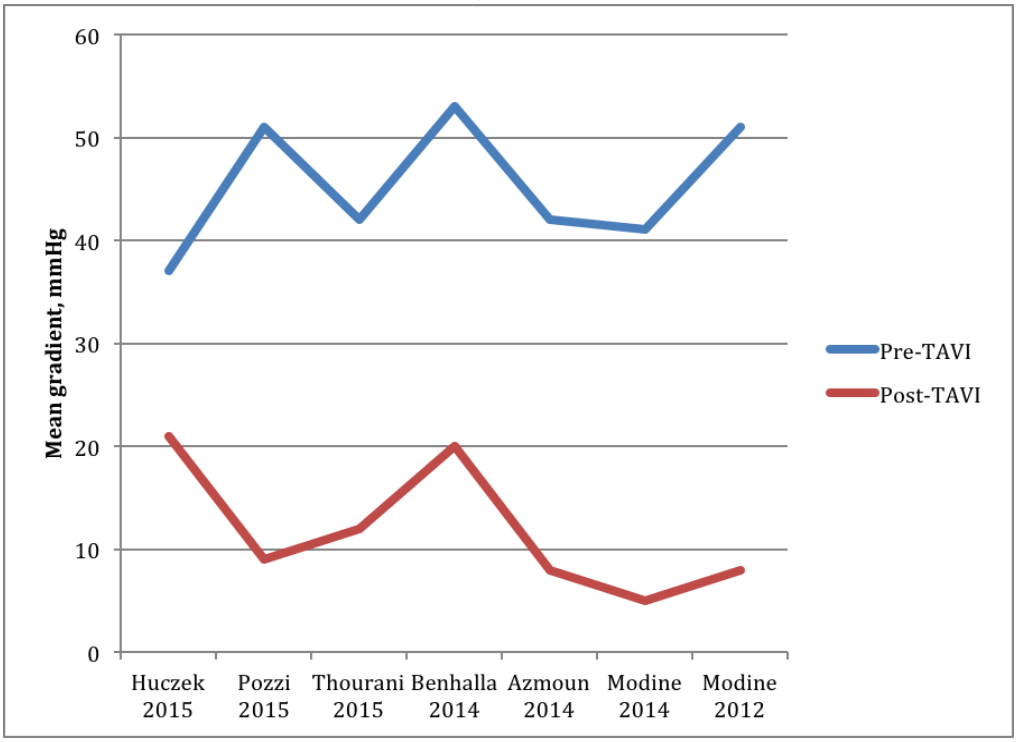

Figure 2 shows the improvement in the mean gradient (mmHg) across the aortic valve before and after the TAVI procedure. It shows a satisfactory improvement in all 6 studies that reported this data.

3.7 Follow-up and outcome

There was variation across the studies in terms of follow-up timeline and outcomes assessed, as seen in **Table 4**. Follow-up varied from 30 days to one year and typically symptomatic improvement or echocardiographic improvements were reported. Nine studies reported change in NYHA score as an outcome, with all of these showing an improvement, with a return to NYHA Class 1 seen in eight of these studies from a baseline of NYHA Class 3 or 4.

Table 4. Outcomes

First author; Year	Assessment of valve post-procedure	Aortic regurgitation (Paravalvular and Transvalvular)	Hospital stay post-op (days)	Follow-up	Mortality	Neurological complications	Required pacemaker	TAVI-related complications according to VARC-2	Result at Follow-up
Huczek 2015	Mean valve area 1.1cm^2, mean gradient 21mmHg.	No	7	-	No	No. DW-MRI post-op showed no pathological changes	No	No	Improved functional status – NYHA 1
Huczek 2015	Mean valve area 1.6cm^2	Trivial PVR	6	-	No	No clinical neurology. DW-MRI day 3 post-op showed small new ischaemic lesion in right frontal lobe	No	No	Improved functional status – NYHA 1
Daly 2015	No residual gradient or aortic regurge. Normal MVR function. Normal function TAVI. Mean valve area 1.8cm^2, mean gradient 12 mmHg, jet velocity 2.0m/s. Optimally positioned.	Trivial PVR	7	Cardiac gated CT 30 days post op. Clinical and ECHO follow up 1 year post op.	None at 1 year f/u		New pacemaker implanted for slow AF and new intermitted LBBB		Improved function status - NYHA 1.
Huber 2015	Mean valve area 1.8cm^2, mean gradient 6 mmHg.	Mild PVR at 30 day f/u	-	Echo 30 days + 6 months	None at 6 month f/u	No	No	None at 6 month follow-up	NYHA I. Doppler US of the access vessel at 6 months showed no normal flow patterns with no stenosis or vascular lesion.
Huber 2015	Mean valve area 2.2cm^2, mean gradient 3 mmHg	Mild PVR at 30 day f/u	-	Echo 30 days + Doppler US 6 months	None at 6 month f/u	No	No	None at 6 month follow-up	Normal LV EF at 6 months.
Huber 2015	Mean valve area 1.8cm^2, mean gradient 6 mmHg.	Mild PVR at 30 day f/u	-	Echo 30 days + Doppler US 6 months	None at 6 month f/u	No	No	None at 6 month follow-up	NYHA I. Doppler US of the access vessel at 6 months showed no normal flow patterns with no stenosis or vascular lesion.
Pozzi 2015	Good valve function in all pts. Mean gradient 8.8 ± 3.1 mmHg, mean aortic jet velocity 2.06 ± 0.34m/s	1 pt with residual PVR n≥2	Mean 9 +/- 3.3 (Range 6-15)	TTE within 24 hours, 1 week, 4 weeks.	None at 30 day f/u	Spatial-temporal disorientation with confusion and agitation - cerebral CT showed not sign of stroke.	2 (22.2%) permanent pacemaker insertion due to third-degree AV block	3 pts required 2 units of packed red blood cells (already Hb <13 pre-procedure). 1 left groin haematoma (from temporary pacing lead insertion). 1 pt required post deployment balloon dilatation. No other TAVI-related complication.	-
Thourani 2015	Mean valve area 1.52 ± 0.35cm^2, mean gradient 11.7 ± 4.0mmHg, peak gradient 22.9 ± 8.6mmHg, jet velocity 2.3 ± 0.5 m/s	PVR trace n=9 (81.8%), mild n=2 (18.2%).	Mean 11 +/- 9.2	ECHO & clinic at 30 days	None at 30 day f/u	No	No	1 pt required new dialysis. 6 pts (54.6%) required transfusion of packed red blood cells (1.09 units +/- 1.14). 2 (18.2%) pts required platelet transfusion.	-
Benhalla 2015	Mean valve area 1.1cm^2, mean gradient 20mmHg	-	-		No	No	No	No	Improved dyspnoea at 1 week & 1 month
Azmoun 2014	Mean gradient 8 ± 4mmHg	No PVR n=8 (44.4%), mild n=9 (50.0%), moderate n=1 (5.3%).	Mean 4.6 +/- 2.3	TTE within 24 hours, before discharge and at 1 month.	30 day mortality 2 deaths (10.5%). 1 intraoperative death by annulus rupture during preimplant balloon valvuloplasty. 1 in	Loss of consciousness on cross clamping in 2 pts (resolved with passive antegrade carotid perfusion)	3 pts required permanent pacemaker insertion for third-degree atrioventricular block	4 pts required transfusion 2 units packed red cells (all with baseline Hb <10). No other TAVI-related complications.	

					hospital death due to multisystem organ failure (Post op day 6 in 83 year old with poor preoperative condition Euroscore 32,STS 15.6, EF 25%).				
Maureira 2014	Mean gradient 15 mmHg, LV EDD 65mm, LV EF no change.	No PVR, No AR	4	TTE at 6 months	No	No	No	No	Improved exercise tolerance
Modine 2014	Mean gradient 5mmHg, jet velocity 1.6m/s, normal LV EF.	No AR	7	Carotid Doppler at 7 days. ECHO & clinic at 1 year.	No		Permanent pacemaker insertion due to LBBB and 1st degree heart block		Improved dyspnoea - NYHA II at 1 year. Normal carotid Doppler at 7 days & 1 year.
Rajagopal 2014	-	Mild PVR			No	No		No	
Magalhaes 2013	-	Mild PVR	8	3 month clinic F/U	No	No	Permanent pacemaker insertion due to new onset LBBB and temporary complete heart block	-	Improved dyspnoea - NYHA I. No further presyncope
Khan 2013					No peri-procedural death. 1 death Day 20 post discharge related to haemopericardium related to valve implantation.	No peri-procedural	None		
Guyton 2013	-	-	6	-	No	No	-	-	Symptomatic improvement at discharge.
Guyton 2013	-	-	5	-	No	No	-	-	-
Guyton 2013	-	-	9	-	No	No	-	-	-
Modine 2012	Mean gradient 8 mmHg (range 4-12mmHg)	Trivial PVR n=12 (100%) at 30 day f/u		TTE within 24 hours,1 week and 4 weeks.	No	1 pt had a contralateral TIA	1 pt required permanent pacemaker insertion due to severe bradycardia (2 days post-op)	No	-
Mouillet 2011	-	Grade 1 (moderate) AR.	4	6 months	No	No	No	No	Good clinical condition. Improved dyspnoea - NYHA I.
Modine 2010	-	No AR		1 month	No	Transient right hemiparesis. CT showed no ischaemic or haemmorhagic stroke.	No	Intraoperative dissection (a partial noncircumferential retrograde dissection of the left carotid artery and ascending aorta on guide wire insertion). CT angio and doppler showed complete resolution	Improved dyspnoea - NYHA II.

Table 4 Abbreviation List	
PVR	Paravalvular regurgitation
MVR	Mitral valve regurgitation
TAVI	Transaortic valve implantation
LV EF	Left ventricle ejection fraction
TIA	Transient ischaemic attack
LBBB	Left bundle branch block
AV	Atrioventricular
NYHA	New York Heart Association
DW-MRI	Diffusion-weighted MRI
pt	patient
pts	patients
f/u	Follow-up

Table 4 shows the outcomes reported by each study both in terms of assessment of the new valve but also complications post-operatively and the patients welfare at follow-up.

4. Discussion

This systematic review has looked to summarise the current evidence base for carotid access TAVI with a view to assessing its safety and feasibility as an alternative access route. The primary considerations are complications that relate directly to the access route – mortality, neurological complications and vascular access complications. The secondary aim is to show non-inferiority with regard to prosthetic valve placement in terms of outcomes related to valve replacement.

4.1 Mortality

The overall mortality for the patients included in the review was low – one intraoperative death and a further two within 30 days. This mortality rate of 4.1% compares favourably with those reported for the transfemoral and transapical approach in a large meta-analysis by Li and colleagues (7.5% and 11.3% respectively) (25).

This mortality rate is particularly notable considering that carotid access, in many institutions, is seen as a last resort for patients unsuitable for other access techniques. The chief reasons for selection of carotid access over other techniques in this review were peripheral vascular disease, unsuitable anatomy, poor pulmonary reserve and prior coronary bypass using the internal mammary artery.

4.2 Neurological complications

Two transient ischaemic attacks were reported but there were no permanent strokes (2.8%). The large meta-analysis by Li and colleagues showed stroke rates at 30-day follow-up to be 3.8% in transfemoral and 4.0% in transapical access routes respectively (25). This suggests the stroke risk for carotid access is comparable to other TAVI access routes. Azmoun and colleagues have even suggested that stroke risk may be lower as the aortic arch is not instrumented and one of the carotid arteries is clamped during the procedure (15).

There was no consensus on the use of neurological monitoring. Cerebral oximetry was the most commonly used – in six studies (8, 14, 18-20, 23). Azmoun and colleagues preferred awake testing over CO monitoring as the physician can monitor the patients' neurological status allowing rapid detection of changes (15). It also allowed for a 'cross-clamp test' to be performed, which if failed, allowed the placement of a temporary carotid shunt similar to standard carotid endarterectomy practice under local anaesthetic (26, 27).

Huczek et al. were the only study to use transcranial Doppler monitoring (TCD), an established method of judging cerebral embolic load during procedures, followed by postoperative diffusion-weighted MRI to look for silent neurological damage (6). They found 160 and 200 high intensity signals (HITS), equivalent to cerebral embolic load, in their two cases - mostly during prosthesis deployment. In their second case they discovered a silent ischaemic lesion in the right subcortical area of the front lobe. A recent study by Alassar and colleagues found

a mean cerebral load of 134 (range 76-244) in 85 TAVI (via mainly transfemoral route, but also subclavian and transaortic) (28). They also found 76% of cases had ischaemic lesions on DW-MRI at 6 days. This suggests that silent ischaemic lesions are commonplace in TAVI procedures and the cerebral load seen in carotid access procedures appears comparable.

4.3 Vascular access site complications

There was one incidence of intraoperative dissection of the aorta and left carotid artery on insertion of the guide wire, in the first case report (10). This did not require abortion of the procedure and was shown to be completely resolved following the procedure with the patient having a good final outcome. In transfemoral access TAVI aortic dissection is reported in up to 2% of patients, while rates of iliofemoral dissection can be as high as 7.4% when a surgical cutdown is used and 21.4% with percutaneous closure (29).

There was one incidence of a vascular access site complication - a femoral haematoma from insertion of the pacing wire (8). Importantly there were no vascular access site complications at the carotid. This is promising and appears comparable with incidence rates of 2 to 18% in large series studies on transfemoral TAVI (29). Furthermore there were no cases of access site infection, seen in up to 6.3% of transfemoral access cases (29), and this is reflective of infection rates following carotid endarterectomy which are less than 1% (30).

4.4 TAVI-related complications and outcomes

Specific TAVI-related complications and outcomes are well reported in the literature for transfemoral access (31) and a secondary consideration of this review is whether carotid access has a negative impact on these.

Rates of pacemaker insertion (12.2%), myocardial infarction (0 patients), acute kidney injury requiring new dialysis (1 patient), need for transfusion (10 patients) found in this review were all comparable to those seen in a study of 270 patients undergoing TAVI via a transfemoral route (32).

The rate of moderate or severe paravalvular regurgitation was 4.1%. Thourani and colleagues found comparable rates of moderate or severe paravalvular regurgitation in 2.2% of patients undergoing TAVI via a transapical route and 2.9% via a transaortic route (19). 4.1% also compares favourably with a moderate or severe paravalvular regurgitation rate of 11.8% seen in the PARTNER trial in patients undergoing TAVI via transfemoral access (33).

The six studies that reported transvalvular mean pressure gradient pre- and post-procedure all showed a satisfactory improvement in valve function (8, 15, 17-20). Similarly, all studies that reported outcome at follow-up stated an improvement in NYHA classification or other symptomatic improvement.

These findings suggest that there is no negative impact on valve placement via the carotid access route. This is further supported by qualitative reports that

carotid access provides a more accurate sheath delivery and stability, better movement precision, more direct access and a more accurate prosthesis positioning (13, 15, 20, 34).

4.5 Surgical technique and equipment

There is currently no consensus as to which carotid side is preferred. Some studies championed the left carotid as it offered a more direct approach (8, 18, 24), others the right carotid due to favourable angulation (13, 23) and finally some sides were selected based on individual patient anatomy established on pre-operative imaging (14, 15, 22). This case-by-case decision-making based on the individual anatomy and surgeon preference seems to be the most sensible method at this time given the paucity of data.

General anaesthesia carries well-known risks in elderly and frail patients, and this is often the same patient population that require TAVI as they are unfit for open surgery. Research has shown local anaesthetic to be safe and efficient for internal carotid endarterectomy (26). Gurer and colleagues showed that it reduced operation time, shunt usage, hospitalisation time and permanent stroke rates in this procedure (27). 23 patients underwent TAVI via carotid access under local anaesthetic in this systematic review. The feasibility of carotid access via local anaesthetic increases its appeal as, unlike the other 'alternative' access routes, it does not automatically preclude those patients unfit for general anaesthetic.

4.6 Limitations of evidence

There are four key limitations to the data presented. Firstly the current evidence available is composed of case reports, case series and cohort studies only, with no randomized control trials to date. Secondly the total sample size of 72 patients is small. Thirdly the follow-up is heterogeneous across the studies with some not reported, some reviewed at 30-days and some followed-up for one year with no data beyond that timeframe. Finally the possibility of positive reporting or publication bias cannot be excluded which may have resulted in cases with poor outcomes not being reported in the literature.

4.7 Implications for practice

Accepting the limitations of the data discussed this systematic review suggests that carotid access provides a safe and feasible alternative access route for TAVI. Mortality, neurological complications and vascular access complications are comparable to the currently accepted access routes. While TAVI-related outcomes such as pacemaker insertion, general complications and echocardiographic outcomes are also non-inferior based on these data.

Carotid access will offer an alternative access route to a subset of patients who, due to co-morbidities, are currently ineligible for other procedures and this is worth further exploration.

4.8 Implications for research

Given the safety and feasibility of this access technique further research in the area is required. This should chiefly set out to address the limitations of the current data set, as described above. Future studies should be randomised controlled studies with a larger patient sample and follow-up at 30 days and 1 year. They should clearly report the valve characteristics pre- and post-procedure, and again at 1 year follow-up. All complications should be reported according to the VARC-2 guidelines (12). These changes will give a more complete dataset and will give a more robust evidence base to support carotid access as an alternative route for the TAVI procedure.

5. Conclusion

Transcatheter aortic valve implantation (TAVI) via carotid access should be considered a safe and feasible alternative when transfemoral access is not available. This systematic review shows promising results for mortality, neurological complications and vascular access complications from data on 72 patients. Furthermore there is no obvious negative impact in terms of results from valve implantation. This creates an opportunity for a subset of patients to have a valve replacement that may not previously have been possible.

Further research, ideally in the form of randomised controlled trials, should seek to support these findings and answer whether this technique should become the first alternative to transfemoral access or even the primary TAVI access route.

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